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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/914,658      | 02/15/2002  | Gerd Hobom           | Kreisler 1098-KGB   | 2342             |

7590 01/15/2004

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EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                              |  |
|------------------------------|-------------------------------|------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/914,658 | Applicant(s)<br>HOBOM ET AL. |  |
|                              | Examiner<br>Stacy B Chen      | Art Unit<br>1648             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.  
     4a) Of the above claim(s) 23 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24-26 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on August 31, 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☒ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's election of Group I, claims 1-22, 24-26 and 28-30, with traverse, is acknowledged. Applicant argues that the Groups have unity of invention and thus the restriction requirement should be withdrawn. While the claims may have unity of invention, pursuant to 37 CFR 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Therefore, the restriction requirement is deemed proper and made FINAL. Claims 1-30 are pending. Claims 23 and 27 are withdrawn from consideration, being drawn to non-elected inventions. Claims 1-22, 24-26 and 28-30 are examined.

### ***Specification***

2. The specification contains nucleotide sequences that are not referred to by a SEQ ID NO on page 11, for example. All sequences must be referred to by a sequence identifier and accompanied by a sequence listing, computer readable form (CRF) and statement that the paper sequence listing and CRF are identical.

### ***Claim Objections***

3. Claims 9 and 10 are objected to because of the following informalities: Claims 9 and 10 recite nucleotide sequences but fail to refer to a SEQ ID NO. The Office notes that the sequence in claim 9 is found in SEQ ID NO: 26, and that the sequence in claim 10 is found in SEQ ID NO: 15. Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 24-26 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 1 and depending claims, “high-yield expression” and “overall convergent arrangement” are indefinite phrases. “[H]igh-yield expression” is a relative term whose metes and bounds are not defined. “[O]verall convergent arrangement” is also a relative term since it is not clear what the metes and bounds of “overall” are meant to encompass.
- In claim 1 and depending claims, “(ambisense RNA segment)” is indefinite because it is not clear whether the limitations following the phrase are part of the claimed invention. Parentheses should be removed to avoid confusion over whether or not ambisense RNA is an example, or the actual embodiment being claimed.
- In claim 1 and depending claims, “regular viral RNA segments” is unclear because “regular” is a relative term whose metes and bounds are not defined.
- In claim 1 and depending claims, do the “standard viral genes” belong to the influenza virus or the foreign sequence?
- Claim 4, “the standard components” lacks antecedent basis in claims 1 and 3.

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- In claim 5 and depending claims, “improved transcription rates” is indefinite because it is a relative term whose metes and bounds are not defined.
- In claims 6-10 and depending claims, “the 12 nucleotide conserved influenza 3’ terminal sequence” and “the 13 nucleotide conserved influenza 5’ terminal sequence” lack antecedent basis in claims 1 and 5.
- In claims 6, 7, 8, 10 and depending claims, the sequence positions 3, 5 and 8 are not in the context of a larger sequence that is known. The positions should be referred to in a sequence identifier so that they can be searched relative to a defined sequence.
- Claim 13, “proteins or artificial polypeptides designed to support an efficient presentation of inherent epitopes” is unclear. How are the proteins or polypeptides “designed”? Is there any modification taking place in the design of the proteins or polypeptides? What is meant by “support an efficient presentation”? How do the proteins or polypeptides “support” presentation? Is there a function that the proteins or polypeptides perform in order to “support” presentation? Further, “efficient” is a relative term whose metes and bounds are not defined.
- Claim 14 lacks method steps that show the completion of production of recombinant influenza. The method requires a step indicating that the viruses are actually made.
- Claims 18-22, 24-26 and 28-30 lack method steps that show how a recombinant influenza virus is used in the methods. While all of the technical details of a

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method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination.

- Claim 22, “application schemes” is unclear because the metes and bounds of “schemes” is not defined. What are “schemes” and what method steps are associated with them?


### ***Conclusion***


5. No claim is allowed. The subject matter of the claims regarding the use of an ambisense RNA segment appears to be free of the prior art. The closest prior art cited but not relied upon is Hobom *et al* (WO 96/10641) which discloses a method of expressing influenza vRNA molecules coding for chloramphenicol acetyltransferase in anti-sense orientation via RNA polymerase I transcription *in vivo* in transiently DNA-transfected cells (abstract). Hobom fails to teach an ambisense RNA segment, which generates viral RNA (RNA polymerase I) and mRNA (RNA polymerase II) from one template using a bi-directional transcription construct. Hoffmann *et al* (*Virology* 267:30-317, 2000), not available as prior art because the instant application claims priority to March 6, 1999, discloses an ambisense approach for the generation of influenza A virus.

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Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Stacy B. Chen  
January 9, 2004

  
JAMES HOUSEL  
1/12/04  
PATENT EXAMINER  
GROUP 1600 CENTER 1600